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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,966	12/03/2003	Catherine A. Pipenhagen	47563.0012	4374

57600 7590 04/10/2007  
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EXAMINER
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WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/726,966

Applicant(s)

PIPENHAGEN ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33, 37-40 and 42-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 14-23, 25, 28, 29, 31, 33, 37-40, 42, 43 and 45-52 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 9-13, 24, 26, 27, 30, 32 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 25, 2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5, 8, 14-18, 23, 47, 49, 50, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681) disclose, at least in figures 1-4 and in col. 5, lines 6-40; a tissue puncture closure device and a method of sealing an internal tissue puncture with the device, where the device has a carrier tube (104), a filament (34D), an anchor (32) or internal component, a sealing plug (30 and/or 36) or external component positioned in the carrier tube, where the filament passes from a first hole in

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the sealing plug (e.g. 30A (or 36A in element 36)) or external component to a hole in the anchor (32B) or internal component and back through a second hole in the sealing plug (e.g., 30B or 30C (or 36B in element 36)) or external component, where the sealing plug (30) is folded between the first hole (30A) and the second hole (30B), where the sealing plug and filament comprise biologically resorbable materials, where the sealing plug shape comprises two components (30, 36) or the external component includes elements 30 and 36 as respective first and second external components, where the sealing plug comprises a folded collagen sponge, where the sponge is folded twice longitudinally (i.e., compressed in a longitudinal direction), where the sponge is substantially S-shaped (if viewed from a side opposing the view of fig. 3), where the sealing plug fills an internal tissue puncture, where the anchor and sealing plug (or closure device) are inserted into an insertion sheath (100 or 104), wherein the tissue puncture sealing device is in an undeployed configuration (i.e., the external component is held in a folded configuration by the presence of sutures in the passageway of the external component, so that one portion of the external component is in contact with another portion of the external component at the folds); and where the tissue puncture closure device is a vascular puncture closure device with the anchor being configured to be inserted through an opening in a blood vessel and the sealing plug is configured to be opposite the anchor outside of the blood vessel, and where in the filament is configured to couple the anchor and the sealing plug (see fig. 3).

4. Claim 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Rousseau (6,425,924). Rousseau discloses, in figures 1-4, a tissue puncture closure

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device in an undeployed configuration having a filament (22), an anchor (distal element 14), a flexible sealing plug (another, proximal element 14 and 26), where the sealing plug comprises first (at 26) and second (at 14) pluralities of openings (the cells of the meshes), and where the filament passes through at least two openings from the first plurality of openings (at 26 and 14), through the anchor, and back through at least two openings from the second plurality of openings (at 26 and 14), and where the sealing plug is folded (at proximal element 14).

5. Claims 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Thal (5,720,765). Thal discloses, at least in figures 5a and 5b and in col. 7, lines 5-21, a tissue puncture closure device including an anchor (50 or 58), a flexible sealing plug (54), and a filament (52), where the sealing plug is generally X-shaped in cross-section, where the sealing plug is formed of an inherently flexible (i.e., elastic) polymeric or suture material, and where the sealing plug is configured to change shape upon being coupled to the anchor with the filament (i.e., by welding of the filament to the sealing plug).

6. Claims 15, 19-22, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (5,545,178). Kensey et al. disclose, at least in figures 1-9, a tissue puncture sealing device including an internal component (38), an external component (36) that is folded so that one portion of the external component is in contact with another portion of the external component (see fig. 6), and a filament (42), where the filament passes from a first hole in the external component (50) to a hole in the internal component (54 or 56) and back through a second hole (48) in the external

component, where the tissue puncture device is in an undeployed configuration where the tissue puncture device is not inserted into a patient's tissue; where the external component comprises a plurality of holes (including the first and second holes and the cells of a weave) forming a weave pattern (52), where the filament weaves through a first portion of the weave pattern, through the internal component, and back through a second portion of the weave pattern (see figs. 6 and 9); where the external component is folded between the first and second portions of the weave pattern (see fig. 6), where first and second portions of the external component comprise two legs of a general V-shape folded latitudinally along a centerline such that the two legs are substantially aligned (see fig. 9), and where the sealing plug is folded from an original V-shape (see fig. 6) to a rectangular shape (see fig. 1). Also, Kensey et al. disclose a tissue puncture closure assembly including an insertion sheath (34) and a carrier tube (32).

7. Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by Akerfeldt et al. (6,508,828). Akerfeldt et al. disclose, in figures 1 and 6-18, a tissue puncture closure device or assembly having a carrier tube (24), a filament (12), an anchor (2), a sealing plug (18) that is folded at least once (as seen fig. 18, and closed as seen in fig. 1), where the tissue puncture closure device is not inserted into a patient's tissue.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmieding (6,027,523). Schmieding discloses the invention substantially as claimed. Schmieding discloses an internal tissue puncture closure device including an anchor (50, 52, 54, or 56), a filament, and a flexible sealing plug (42), where the sealing plug includes two cross members, and where the sealing plug is formed of PLLA or DELRIN, which are inherently flexible (i.e., elastic) polymeric materials. However, Schmieding does not disclose that the filament extends through a plurality of holes in each of the two cross members. Nevertheless, Schmieding discloses a sealing plug (4) with a plurality of holes for receiving filaments (6, 36). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to include a plurality of holes in each of the two cross members. Such holes would allow convenient attachment of filaments to the sealing plug, while allowing at least two portions of a filament or two filaments to securely connect the sealing plug (and tissue) to the anchor.

10. Claims 37-40, 42, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (6,508,828). Akerfeldt et al. disclose the invention substantially as claimed. Akerfeldt et al. disclose, in figures 1 and 6-18, a tissue

puncture closure device and a method of sealing an internal tissue puncture having a carrier tube (24) or insertion sheath, and a closure device including an anchor (2) and a sealing plug (18) that is folded at least once or from a V-shape (fig. 18) into a substantially straight shape, and a filament (12). However, Adkerfeldt et al. do not disclose that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug, when the closure device is in an undeployed configuration before insertion into the internal tissue puncture (see fig. 8). Akerfeldt et al. also do not disclose that the sealing plug is in a V-shape when open and laid out flat. Nevertheless, Akerfeldt et al. disclose, in figures 15 and 17, that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug when parts 41 and 42 are moved along filament (12). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to move parts 41 and 42 within the carrier tube (as shown in figures 8, 10, and 11), so that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug (while the closure device is in an undeployed configuration within the carrier tube). Such a narrowed configuration of the sealing plug would ease its deployment through a puncture in a vessel.

Akerfeldt et al. also disclose, in col. 5, lines 4-7; that the sealing plug (18) comprises a polymeric material conforming to a suture (12) and is a thickened portion of a suture formed into a V-shape. Thus, it would have been obvious to one having ordinary skill in the art to form the sealing plug into a V-shape while the suture is open



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and laid out flat in a V-shape. Such a pre-formed shape for the sealing plug and suture would ease the assembly of the components of the device before its insertion into a tissue wall puncture.

***Allowable Subject Matter***

11. Claims 6, 7, 9-13, 24, 26, 27, 30, 32, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses a tissue puncture closure device having, inter alia, a carrier tube, a filament, an anchor, and a sealing plug or first external component, and a second external component folded and engaged with the first external component, where the sealing plug comprises a first plurality of holes forming a first weave pattern and a second plurality of holes forming a second weave pattern, where the filament passes through each one of the pluralities of holes; where the sealing plug comprises an X-shape in cross-section, where the external component is collagen sponge folded into legs of a general V-shaped folded along a centerline or where first and second external components are each folded into generally U-shapes; where the filament alternately extends through holes in two cross members of the sealing plug in a spiral pattern, where flexible sealing plug has two legs forming a symmetrical shape with first and second pluralities of openings in each respective leg; and where the sealing plug is tri-folded into an S-shape as seen from an end view.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Response to Amendment***

13. Applicant's arguments filed on August 7, 2006 have been fully considered but they are not fully persuasive: See the restated and new grounds of rejection above. The rejections of claims under 35 U.S.C. 112, 2<sup>nd</sup> paragraph and under 35 U.S.C. 103(a) regarding the references of Rousseau and Himpens et al., are hereby withdrawn.

With respect to argument regarding the rejection of claims under 35 U.S.C. 102 and the reference of Nash et al.: Nash et al. indeed disclose passing of a filament from a first hole in the sealing plug to a hole in the anchor and back through a second hole in the sealing plug (e.g., 36). If the sealing plug is deemed element 30, then the filament's return to the second hole is via the first hole. Also, figure 2 shows that element 30 is folded in an undeployed configuration.

With respect to arguments regarding the rejection under 35 U.S.C. 102 with the Rousseau reference: See the restatement of the rejection above, where the filament indeed passes through at least two openings from each of the first and second pluralities of openings of the flexible sealing plug.

With respect to arguments regarding the rejection under 35 U.S.C. 102 with the Thal reference: The sealing plug is said to be formed from the same polymeric, elastic material as applied in suture. The suture or suture material is flexible. Therefore, the sealing plug is flexible (but more rigid relative to the filament). Moreover, the sealing

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plug indeed changes shape upon coupling to the filament, for welding causes a portion of the sealing plug to meld with a portion of the filament, thus altering the original shape of the sealing plug.

With respect to arguments regarding the rejection under 35 U.S.C. 102 with the reference of Akerfeldt et al.: The sealing plug (18) is open and V-shaped, since it conforms to the contours of a suture that can be laid out flat (e.g., on a horizontal working surface) in a V-shape or as shown in the plane of figure 1, for example. Also, the top portion of the V-shape can broadly be described as "open."

With respect to arguments regarding the rejection under 35 U.S.C. 103 with the Schmieding reference: PLLA and DELRIN, indeed, are flexible or elastic, polymeric materials. Schmieding only discloses that the sealing plug, made of one of these materials, is apparently more rigid than the filament, but the sealing plug is "flexible" nonetheless.

With respect to arguments regarding the rejection under 35 U.S.C. 103 with the reference of Akerfeldt et al. and in contrast to Applicant's arguments: The Examiner did not assert that parts 41 and 42 are folded in the insertion sheath. The rejection did assert that the positioning of parts 41 and 42 next to each other results in the folding of the sealing plug (18), so that portions of the sealing plug contact each other.

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***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo  
Primary Examiner

April 4, 2007